

### **REMARKS**

Claims 22 and 30 are currently pending in the present application. Claims 22 and 30 are the only claims in independent form.

Claim 25 stands rejected under 37 C.F.R. 1.75(c) as being in improper dependent form for failing to further limit the subject matter of the previous claim. In order to further prosecution, claim 25 has been canceled without prejudice. Reconsideration of the rejection is respectfully requested.

Claim 22 stands rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action has held that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office Action has held that the instant specification does not disclose "a suppository" that "consists of" only valproate, sodium valproate, or valproate salts. The specification discloses at page 12, line 24 through page 13, line 14, wherein there is disclosed that, an "embodiment of the present invention is a suppository 38 that includes a medication composition 16 having an effective amount of a medication for effectively treating a migraine attack....The main medication used with the suppository 38 is valproate and other valproate derivatives and/or salts thereof." The passage also discloses details with regard to the suppository and substances that are part of the suppository; however, it is respectfully submitted that the additional components that the Office Action references are not in addition to the suppository and medication but instead are included within the parameters of the suppository. Since the suppository is disclosed in the specification and is broadly recited in the claims that the suppository can include numerous compositions is not limited by the claim language and reconsideration of the rejection is respectfully requested.

Claims 22 and 30 stand rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for making and/or using a suppository

composition comprising valproate, sodium valproate, or valproate salts, and other pharmaceutical carriers, does not reasonably provide enablement for making and/or using a suppository composition consisting of only valproate, sodium valproate, or valproate salts. The claims have been amended to more specifically recite that the suppository includes a pharmaceutically acceptable carrier, thereby overcoming the present rejection. The pharmaceutical carrier is any carrier known to those of skill in the art including those discussed on page 7 of the outstanding Office Action. Reconsideration of the rejection is respectfully requested.

Claims 22 and 30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action has held that the pending claims recite limitation without proper antecedent basis. The claims have been amended to provide proper antecedent basis and reconsideration of the rejection.

Additionally, the Office Action has held that claim 22 recites the term “suppository” but that the term is vague. In order to further prosecution, claim 22 has been amended to recite a pharmaceutically acceptable carrier, thereby overcoming the rejection by the Office Action that the term “suppository” cannot include a pharmaceutical carrier. Reconsideration of the rejection is respectfully requested.

Claim 22 stands rejected under 35 U.S.C. §102 as being anticipated by the Bauer, et al. patent. Reconsideration of the rejection under 35 U.S.C. §102(e), as anticipated by the Bauer, et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: “For prior art to anticipate under §102 it has to meet every element of the claimed invention.”

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action holds the instant independent claim recites a medicine suppository consisting of valproate and salts thereof for the treatment of migraine. It is respectfully submitted that the prior art reference does not disclose a medicine suppository consisting essentially of a medication selected from the group consisting of valproate, sodium valproate, and valproate salts for treating migraine. At best the prior art discloses oral administration of the compound for preventing, not treating migraine. There is further no suggestion for the use of valproate, sodium valproate, and valproate salts in a suppository form for treating migraine. The Office Action held in the above rejections that the suppository is difficult to formulate, it is therefore not obvious to create such a suppository based upon the disclosure in the Bauer, et al. patent. Since, the Bauer, et al. patent does not disclose or suggest the suppository of the presently pending independent claim, the claim is patentable over the Bauer, et al. patent and reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Van Hoogdalem et al., reference in view of the Raskin reference. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over the Van Hoogdalem et al., reference in view of the Raskin reference, as applied to the claims is respectfully requested.

The Office Action has held that the Van Hoogdalem et al., reference discloses rectal drug administration of various drugs, but that there is no disclosure of the use of a valproate suppository to treat migraine. As a secondary reference, the Raskin reference, discloses the use of valproate sodium for the prevention of migraine, wherein the conclusion is that the combination of references teaches the claimed invention. However, in order for an obviousness rejection to be appropriate, there must be some teaching or suggestion for the combination of references. The secondary reference was published three years after the primary reference, yet there

is no teaching of the use of a suppository for treating migraines in either reference. At best the prior art references disclose oral administration of the compound for preventing, not treating migraine. Further, there is no other reference provided that teaches the claimed invention despite the fact that the application was filed in 2002, over ten years after the publication of the first reference. In other words, if the invention was obvious, one of skill in the art, in the ten years since the publication of the primary reference, would have developed the claimed invention. The lack of such a teaching establishes the unexpected results obtained by the claimed invention and as such is patentable over the prior art. Reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Sorensen reference in view of the Murata, et al. patent. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over the Sorensen reference in view of the Murata, et al. patent, as applied to the claims is respectfully requested.

The Office Action holds the instant independent claim recites "a medicine suppository comprising," which is open to valproate and other ingredients. The Office Action has held that the Sorensen reference teaches using valproate to treat migraines, but does not teach the use of a suppository for the treatment. Further, the Office Action has held that the Murata, et al. patent teaches such a suppository. It is respectfully submitted that no prior art reference discloses a medicine suppository consisting essentially of a medication selected from the group consisting of valproate, sodium valproate, and valproate salts for treating migraines. At best the prior art discloses oral administration of the compound for preventing, not treating migraine. Since, the Murata, et al. patent does not disclose the suppository without the inclusion of additional compositions, the presently pending independent claim is patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

It is respectfully submitted that the present amendment places the application in condition for allowance as it removes all remaining issues in dispute. Specifically, the amendment follows suggestions set forth in the Office Action and clarifies the

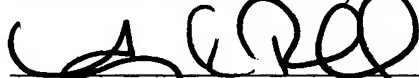
present invention. As a result, no remaining issues are in dispute. Since there is no prior art cited against any of these claims, it is respectfully submitted that all of the claims are in condition for allowance. It is also respectfully submitted that the present amendment places the application in condition for appeal. The claims have not been made broader in scope, thereby requiring no further searching nor raise any new issues. In fact, all claims now include limitations of previously pending claims and were therefore previously searched.

If any remaining issues exist, Applicant respectfully requests to be contacted by telephone at (248) 539-5050.

The Commissioner is authorized to charge any fee or credit any over-payment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

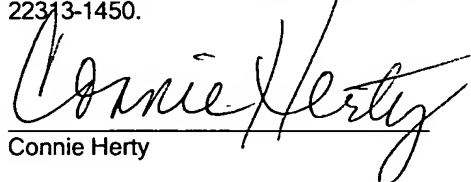


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